AD_____
(Leave blank)

Award Number: W81XWH-08-2-0047

TITLE: Innovative Service Delivery for Secondary Prevention of PTSD in At-Risk OIF-OEF Service Men and Women

PRINCIPAL INVESTIGATOR: Ronald Acierno, Ph.D.

CONTRACTING ORGANIZATION:
Charleston Research Institute
Charleston, SC 29403

REPORT DATE: April 2009

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: (Check one)

X Approved for public release; distribution unlimited

☐ Distribution limited to U.S. Government agencies only; report contains proprietary information

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE *(DD-MM-YYYY)*	**2. REPORT TYPE**	**3. DATES COVERED** *(From - To)*
30-04-2009	Annual	1 April 2008-31 March 2009

4. TITLE AND SUBTITLE

Innovative Service Delivery for Secondary Prevention of PTSD in At-Risk OIF-OEF Service Men and Women

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-08-2-0047

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Martha Strachan, PhD
Ronald Acierno, PhD

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Charleston Research Institute
114 Doughty Street, Room 148
Charleston, SC 29403

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
US Army Medical Research
Fort Detrick, Maryland 1702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for public release; distribution unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

This report describes key research accomplishments for Innovative Service Delivery for Secondary Prevention of PTSD between 4/1/08 and 3/31/09. Previous progress reports detailed the initial, HSRO, Medical University of South Carolina (MUSC), and R&D protocol approval process, the employment and training of study staff, the development of the treatment protocol manual, implementation of study procedures, and the submission of revisions to the protocol (including the addition of two, alternate research sites). This report focuses on the primary objectives for our first year including: a) achieving intra-facility (DOD, MUSC, VHA) compliance, b) the development and implementation of an efficient, sustainable, study-referral infrastructure, c) recruitment and enrollment of active duty participants, and d) refinement of administrative and clinical procedures. Additionally, we provide a detailed description of the study-related activities that occurred between 1/8/09 and 3/31/09. Practical strategies to enhance DOD/VHA research collaborations are discussed.

15. SUBJECT TERMS
PTSD, OIF/OEF, Telemedicine, Behavioral Activation, Therapeutic Exposure, DOD/VHA research collaborations

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
					USAMRMC
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**	UU	29	**19b. TELEPHONE NUMBER** *(include area code)*
U	U	U			

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

Table of Contents

Introduction

Purpose and Scope of the Research Project

The current project has two primary objectives: 1) evaluate the effectiveness of an intervention to prevent the functional impairment associated with PTSD and subclinical PTSD in post-deployed OIF/OEF service men and women, and 2) to determine whether or not this program delivered via telepsychology will be as effective as in-person treatment. Secondary objectives include determining: 1) which treatment modality is more effective in terms of process variables (e.g., treatment satisfaction, session attendance), 2) which treatment modality is more cost-effective, and 3) whether treatment effects differ across race and gender. Behavioral Activation and Therapeutic Exposure (BATE) is an eight-session, manualized treatment program based on two research-supported, therapeutic rationales. Using a between-groups, repeated measures design, study participants will be randomized to one of two treatment conditions: BATE delivered via telepsychology (BATE-T), or BATE delivered in-person (BATE-IP). Participants will be assessed across primary and secondary outcome variables at five time points (pre-treatment, mid-treatment, post-treatment, and 3- and 12-month follow up).

Identification of an effective preventive intervention for PTSD-related symptomatology and functional impairment confers benefits at the patient, medical facility, and military-service level. At the patient-level, this program may reduce emotional suffering, promote better adjustment to post-deployment life, and lead to better mental and physical health prognosis. At the medical facility-level, this program may reduce service-utilization costs associated with untreated PTSD symptomatology (i.e., by reducing risk for development of physical morbidity and psychiatric co-morbidity

associated with untreated PTSD). Furthermore, identification of an innovative service modality (i.e., telemedicine) benefits medical facilities by increasing access to care and reducing costs associated with in-person, individualized therapy. At the military-service level, this program could reduce attrition and medical leave from military service due to PTSD-related functional impairment.

Body

Overview of this report

This report is divided into the following sections: a) Initial Protocol Approval Process, b) Recruitment, c) Key Protocol Revisions, d) Clinical Activities, e) Administrative Activities, f) Personnel Activities, and g) Other Study-related Activities. Previous progress reports detailed the initial, HSRO, MUSC, and R &D protocol approval process, the employment and training of study staff, the development of the treatment protocol manual, implementation of study procedures, and the submission of revisions to the protocol (including the addition of two, alternate research sites). Where possible, we have presented key accomplishments that occurred between 4/1/08 and 3/31/09 in a bullet-pointed format. This report focuses on the primary objectives for our first year including: a) achieving intra-facility (DOD, MUSC, VHA) compliance, b) the development and implementation of an efficient, sustainable, study-referral infrastructure, c) recruitment and enrollment of active duty participants, and d) refinement of administrative and clinical procedures. Additionally, we provide a detailed description of the study-related recruitment activities that occurred between 1/8/09 and 3/31/09 when DoD approval was received.

Although MUSC and the Charleston VA are national leaders in clinical trial research for PTSD, our study represents one of the first DOD- funded therapeutic trials for PTSD at these facilities; we are excited to be at the forefront of this important research collaboration.

This project is under the jurisdiction of three institutional review committees: the Department of Defense, the Veterans Health Administration, and the Medical University

of South Carolina. Although these review boards are governed by a similar principle (i.e., the protection of human subjects), each institution applies specific guidelines and consent requirements to the review process. Although representatives from each facility have provided excellent consultation, presently, there are no centralized guidelines to assist researchers in navigating this intra-facility review process. As such, in addition to completing study-related tasks germane to our roles as clinical scientists, we have worked diligently to develop an infrastructure to facilitate the administrative and compliance-related aspects of this collaboration. Thus, this report reflects key accomplishments in each of these areas (i.e., clinical science, and intrafacility compliance administration).

PART I: Project Initiation Procedures

Initial Protocol Approval Process

Between 4/1/08 and 10/3/08, the protocol was subjected to an extensive submission, review, revision, re-submission, and approval process. Final approvals were received by the HRPO, MUSC IRB, and VA R &D committee on 9/9/08, 9/15/08, and 10/3/08 respectively.

A Summary of Compliance Activities (4/1/08-10/3/08)

Project staff submitted the grant application and study protocol to USAMRMC on 2/7/08. On 2/22/08, project staff discussed the role of the HRPO with representatives from the USAMRMC. On 3/5/08 the HRPO emailed the PI to formally introduce himself, request follow up documentation, and said he would perform a detailed review over the next two to three weeks. On 3/12/08, project staff sent the requested documentation. On 4/1/08, the PI received the award notice.

On 5/20/08, the PI contacted the HRPO to discuss the status of the approval. The HRPO informed the PI that the review had been completed and that he would send the Memorandum for Record (MFR) to project staff as soon as he had received all necessary approvals. On 5/29/08, the PI contacted the HRPO to discuss the status of the MFR. The HRPO informed the PI that the MFR would be sent in one to two business days. On 6/3/08, the HRPO contacted the PI regarding revisions to the protocol, stating that project staff should expect a formal request for revisions in one to two days. On 6/12/08, project staff received the formal request for revisions. The formal response indicated that the protocol review had been completed on 2/7/08, four months prior to project staff's receipt of the first formal request for revisions. Project staff submitted these requests to the HRPO on 6/16/08. On 6/23/08, the HRPO informed the PI that the review would be completed ASAP. On 7/7/08, the HRPO informed the PI that the protocol was on a priority list although final approval had not been granted. On 7/19/08, project staff received the formal response and revisions. Project staff submitted the revised protocol on 7/24/08. The HRPO responded on 8/13/08 and project staff submitted the requested changes on 8/22/08. Final approval was received on 9/9/2008. Project staff submitted the revised protocol to the MUSC/VA IRB on 9/15/08; IRB approval was received 9/18/08. Project staff submitted the IRB-approved protocol to the R & D committee on 9/18/08; approval was received on 10/3/08.

PART II: Recruitment

Current enrollment

We began recruiting subjects on 10/6/08 after receiving R & D approval on 10/3/08. We enrolled our first participant on 10/30/08. Currently, we have screened 51 potential participants. Twenty-two were not eligible to participate because they did not meet inclusion criteria and ten chose to not participate after initial screening. Of the participants screened, 19 have consented to participate in the study.

	Screened		Consented
Apr-08	0*		0*
May-08	0*		0*
Jun-08	0*		0*
Jul-08	0*		0*
Aug-08	0*		0*
Sep-08	0*		0*
Oct-08	3		3
Nov-08	3		3
Dec-08	1		1
Jan-09	12		5
Feb-09	11		3
Mar-09	11		4

***Note that recruitment had not begun during the first six months because we had not received HRPO protocol approval.**

Recruitment of Veterans: Special Considerations for Each Recruitment Site

When conducting empirical research in clinical environments, researchers must be flexible and respectful of standard operating procedures of those clinics. Moreover, because they 'expect' something of the clinics in the form of referrals, care must be taken not to cause clinicians to feel exploited. Initial months of the project were devoted to maximizing the collaboration between clinical and research teams at each study site.

Charleston VA. In November, project staff coordinated with VA administrators and clinicians to develop a two-tiered PTSD assessment clinic (psychosocial interview

conducted by a VA psychologist, followed by structured diagnostic interviews and self reports administered by VA clinical and research staff) that would serve both clinical and research interests. VA health care providers refer *all* patients who endorse PTSD symptoms to the PTSD Clinical Team (PCT) clinic, which is under the direction of the PI of this study. Thus, to identify appropriate candidates for exposure therapy, to increase opportunities for Veterans to receive individual therapy, to maximize opportunities for recruitment, and to provide clinic therapists with valuable assessment data, project staff worked closely with clinic staff to devise the following assessment system: All patients referred to the PCT clinic currently receive a two-part evaluation. First, patients meet with a VA psychologist who administers a brief, semi-structured psychosocial interview, and provides information about the opportunity to participate in our study. Second, patients interested in the study meet with our project nurse immediately following the psychosocial interview. The project nurse provides a more detailed description of the study and completes consent and baseline assessment procedures. Patients who are eligible to participate and who provide consent are immediately randomized to condition and scheduled for their first appointment. Patients who are not eligible to participate because they do not meet inclusion criteria (i.e., patients who are actively abusing substances, suicidal, or psychotic) can then be routed to the appropriate mental health clinic.

This system confers several advantages to the study. First, it provides an efficient mechanism through which potentially eligible veterans (i.e., veterans who have been identified by physicians or other health providers as experiencing PTSD symptoms) can learn about the study, consent to participate, develop rapport with a study staff member,

and complete baseline assessment procedures within a *single time period* (i.e., this mechanism circumvents barriers that may prevent attendance to an additional appointment for study assessment and consent procedures including inconvenience, avoidance, and lack of rapport with study staff). Second, this system facilitates identification of and access to our target population, patients suffering from significant symptoms of PTSD. Given the high demand for individual therapy services, patients are "triaged" to the clinic according to symptom severity; thus, as our functional-impairment prevention-based protocol allows for less symptomatic individuals, patients who would otherwise be waitlisted, can receive immediate treatment. Third, by creating an opportunity for project staff to work in close proximity to and in conjunction with VA clinical staff, we have increased the visibility of the study; VA clinicians now consistently refer patients who might be interested in participating. Fourth, by coordinating baseline assessments with clinical appointments, project staff are able to take advantage of safeguards built into the VA electronic patient reporting system (CPRS) that reduce the likelihood of no-shows. All mental health consults and clinic referrals are routed through CPRS; when physicians submit consults, all other VA clinicians who work with that patient (i.e., social workers, case managers, etc.) are alerted to the fact their patient is scheduled for a PTSD assessment. This often prompts clinicians to provide "gentle" reminders to their patient, as well as work with their patient to circumvent barriers to attendance. Furthermore, CPRS immediately alerts VA administrative staff to schedule the patient for an assessment when a consult/referral is submitted; this reduces lag time between submission of referral/consult and appointment; assessment appointments generally occur within a week of referral/consult submission,

reducing the likelihood that a patient might forget the appointment or reconsider his need for services.

While seemingly straightforward, this integrated intake, assessment, recruitment, and referral system has required significant effort to devise and implement. Meetings to develop, implement, and finalize this assessment system occurred on 11/25/08, 12/2/08, 12/9/08, 12/16/08, and 1/6/09. Importantly, we have increased the number of participants recruited each month since this system was implemented. As illustrated in Table 1, this recruitment mechanism yields a promising enrollment trajectory.

Atlanta VAMC. Additionally, we submitted a protocol revision to include the Atlanta VAMC as an additional site (this protocol revision as well as the revision to add Winn Army Community Hospital as a study site was submitted to the HRPO. We are addressing the second round of HRPO requested (minor) revisions for this request and will re-submit the revisions when all documentation is received from both sites. During the next reporting period, and once HRPO approval for these revisions is obtained, we will focus our attentions on the recruitment of active duty personnel. Once study procedures are implemented and running smoothly at Winn Army Community Hospital, we will initiate procedures at the Atlanta VAMC.

Other VA recruitment activities. Other recruitment activities have included attending weekly VA-sponsored job fairs (Project representatives sit at "Research Opportunity" tables and discuss the study with interested OIF/OEF Veterans), meeting with primary care and mental health care providers to educate them about the study and the opportunity for their patients to participate, and drafting and mailing out VA-approved letters of participation to the facility's roster of OIF/OEF Veterans.

Recruitment of Active Duty Personnel

Recruitment of active duty personnel continues to be the primary objective, Currently, we have secured collaborations with two DOD facilities.

Winn Army Community Hospital. Upon receipt of the award letter, we initiated contact with Major Christopher Warner, Chief of Behavioral Medicine at the Winn Army Community Hospital (WACH), to invite his participation in the project. As of 3/31/09, the addition of WACH as an alternate research site is still pending HRPO approval (we have received Charleston VAMC and MUSC approval to recruit Veterans from this site). Previous quarterly reports detail the progress of our collaboration with WACH, as well as the extensive protocol approval and revision process required by the HRPO, the MUSC IRB, and the Research and Development Committee between 4/1/08 and 12/31/08. This section describes efforts to secure approval for the addition of WACH as an alternate site that were initiated between 1/9/09 and 3/31/09. On 1/16/09, project staff submitted a protocol revision and letter of support to the HRPO to include WACH as an alternate site. The HRPO contacted us on 2/19/09 requesting additional documentation prior to providing approval. We submitted these requests to the HRPO on 2/27/09. Eager to begin recruiting active duty participants to the study, we contacted the HRPO on 3/17/09, 3/24/09, 3/31/09, and 4/7/09 requesting updates on status of our protocol revisions. We received formal notification of the review on 4/8/09. On 4/13/09 we contacted staff at WACH to request the additional documentation. It is our understanding that each change to and request for documentation requires approval from the site commander; thus, we will submit the requested documentation to the HRPO once we have received it from WACH. We expect to receive the requested documentation on or before 5/8/09 when

Major Warner and Captain Parker attend a study-related training. At this time, we will immediately send the requested materials to the HRPO in hopes of implementing study procedures at WACH as soon as possible. Until we receive HRPO approval, study procedures will not be implemented at WACH.

Charleston Naval Hospital. As HRPO approval of recruitment and study procedures at WACH has taken longer than we had hoped, during February and March we developed a strategic plan to recruit local active duty personnel who seek services through the VAMC or through the MUSC for study participation. At the same time (February 2009), after receiving numerous phone calls from local DoD providers interested in learning more about opportunities to refer their patients to the study, project staff developed a collaborative relationship with Dr. Scott Berry, a psychologist at the Charleston Naval Hospital. Currently, the naval hospital does not provide exposure-based treatment for patients experiencing PTSD symptoms; thus, participation in our trial represented a promising treatment opportunity for military personnel in need of care. To address this treatment gap and obstacle to recruitment, study staff coordinated with Dr. Berry and VA administrators to assure approval for this process. We have obtained Charleston VAMC and MUSC IRB approval for this recruitment path, and again are awaiting HRPO approval.

Medical University of South Carolina (MUSC). In March, project staff initiated steps to include MUSC as an alternate research site which would allow the study to take direct referrals from active duty troops who happen to present to MUSC for services, or who learn about this research project through MUSC based listings (e.g., this recruitment does not take place at DoD facilities).

Additional Information. All VA research protocols are submitted to the MUSC IRB and VA R & D committee for approval. Although MUSC IRB approval is required prior to R & D submission, VHA-specific human subjects regulations require VHA-specific consent and HIPAA procedures. This prohibits the use of VA consent documentation with participants who are not VA patients (i.e., in this case, directly-referred, active duty personnel). Thus, although the study is: a) reviewed and approved by the MUSC IRB, and b) staffed by dually affiliated personnel who maintain space at both facilities, we are required to add MUSC as an alternate research site, initiate an additional approval process, and utilize a separate consent form. Although we understand that the addition of MUSC as a study site will require HRPO approval, study staff has coordinated with representatives from the VA R&D committee and the MUSC IRB (see "Administrative Activities" for dates documenting communications) to identify the procedures necessary to initiate this protocol revision process. We will submit this protocol revision to the HRPO together with the other requested changes once we receive documentation from WACH (on or before 5/8/09).

Recruitment Summary

In summary, these efforts are geared to maximizing recruitment for the study, and each has the potential to double recruitment. We feel recruitment goals will be easily met once HRPO approval is granted and we can begin seeing patients from these alternate sources.

PART III: A Key Protocol Revision

Inclusion of participants with PTSD

To maximize the relevance of study findings to real-world, active military and Veteran patient populations, we submitted an amendment to the protocol that would permit the enrollment of participants who meet full diagnostic criteria for PTSD. The amendment was approved by the MUSC IRB on 3/13/09; the revised protocol is currently under review with the HRPO with preliminary verbal approval already received and provisional approval (pending revisions) received.

Justification for inclusion of participants who meet diagnostic criteria for PTSD. Prior to discussion of prevention theory, (below), we summarize justification for this protocol change thusly: It became apparent through discussions with DoD recruitment sites that a majority of their individuals they felt could benefit from this treatment already had the PTSD diagnosis, but were still functioning. In other words, they were in the early stages of the disorder, and had not yet developed significant functional impairment. It is precisely this functional impairment that is now the target of our prevention efforts.

Prevention theory rests largely on the premise that early identification and treatment of at-risk or pre-symptomatic individuals can prevent negative health outcomes. "Effective" prevention programs for physical disorders prevent negative-disease status individuals from acquiring positive-disease status (i.e., an effective HIV prevention program might prevent an HIV negative individual from becoming an HIV positive individual). In this context, positive disease status confers *significant* health disadvantages that are distinct from negative disease status. More specifically, although negative-status individuals may engage in risky behaviors that contribute to poor health

outcomes, positive-status individuals experience a distinct symptom trajectory not shared by negative-status individuals.

Arguably, evaluating the effectiveness of a mental health prevention program according to the "disease status standard" may be misleading. Indeed, the construct of PTSD allows for considerable variability in symptom intensity; thus, the "distinction" between "subthreshold" PTSD and PTSD can likely represent an artifact of self-report biases or assessment scoring procedures, rather than a valid delineation between two "distinct" disorders with two "distinct" symptom trajectories. To make a direct analogy, although HIV positive status *necessarily* confers a symptom trajectory that is distinct from HIV-negative status, it is not at all clear that PTSD positive status confers a symptom trajectory that is necessarily distinct from subthreshold PTSD status. Indeed multiple definitions of subthreshold PTSD derived from multiple scoring algorithms have been used in clinical trials. These definitions are based on seemingly arbitrary scoring differences. An individual who reports that he experiences intrusive thoughts, several times a month with moderate severity is found to meet criteria for PTSD, while another individual who reports that he experiences intrusive thoughts twice a month with significant severity is found to meet criteria for subthreshold PTSD. It is unclear whether an individual who scores a 2/3 on symptom 3A (of the CAPS) is distinctly worse off that an individual who scores a 2/2 on symptom 3A; furthermore, it seems somewhat misleading to characterize an intervention that prevents a 2/2 from becoming a 2/3 as an effective program.

This is because in mental health, meaningful "prevention" often refers to functional impairment not disease status. As alluded to above, individuals classified as

meeting criteria for "subthreshold" PTSD may experience comparable levels of functional impairment as individuals classified as meeting criteria for PTSD. Thus, to the extent that untreated PTSD symptoms contribute to significant mental health comorbidity and physical morbidity, *the effectiveness of this program should be based on its ability to prevent further functional impairment.*

In a real-world context, medical leave and attrition from the military due to PTSD symptoms is far more likely to be a consequence of the degree of functional impairment (i.e., an army captain who is no longer able to effectively lead the unit due to persistent intrusive thoughts about an IED explosion) than a consequence of disease nomenclature or classification as defined by assessment scoring criteria. Indeed, assessment data indicate that this same captain when assessed via structured interview may just as likely meet criteria for subthreshold PTSD as he would PTSD. As such, a more sensitive and accurate evaluation of this program rests on statistically controlling for symptom severity, frequency, and level of functional impairment, rather than on disease classification. Furthermore, employing the functional impairment standard will more closely approximate criteria for decisions concerning medical leave and medical discharge. Although medical leave and eligibility decisions do require diagnosis, we would argue that diagnosis may be more closely related to functional impairment than fulfillment of each symptom criteria.

PART IV: Clinical Activities

Development of Protocol and Related Materials

During the second quarter, project staff attended weekly clinical team seminars lead by our Ph.D. level project coordinator. Meetings covered the following clinical topics: diagnosing subclinical PTSD, best practices for assessment in treating Veterans experiencing combat-related distress, rationale for behavioral activation therapy, rationale for exposure therapy, strategies to enhance treatment compliance, addressing suicidal ideation, protocol for handling suicidal patients, and addressing family members' concerns about combat-related distress.

To increase efficiency and ease of dissemination, project staff created a user-friendly BATE treatment manual. The manual includes session outlines as delineated in the IRB approved protocol. Additionally, project staff in consultation with Drs. Carl Lejuez and Peter Tuerk created valuable "therapist resources." Therapist resources include analogies, scripts, and outlines to assist the therapist in explaining the rationale for behavioral activation and exposure therapy to the patient. These resources also include handouts that cover topics such as avoidance and withdrawal, coping strategies, increasing patient's adherence to treatment, etc. Project staff also created integral supplemental materials to the treatment manual including the Activity Planner Agenda Book. Every patient will be provided with a Planner at the start of treatment. These planners function as agenda books and assist patients by helping them plan activities, monitor the connection between behaviors and mood, and identify patterns of avoidance and withdrawal. Finally, project staff created a discharge packet for patients who have completed the treatment phase. The packets include useful information about area resources, several month's worth of additional planning pages, and contact information for important health care professionals.

Clinical Trainings

During this reporting year, clinical project staff received training in behavioral activation, therapeutic exposure, and CAPS administration. A bullet-pointed timeline of the trainings is provided below.

- 8/27-8/30/08; 10/1-10/5/08: Dr. Carl Lejuez provided a three-day training to project staff in behavioral activation techniques
- 8/30- 8/31/08; 9/27- 9/28/08; 10/4- 10/5/08: Dr Peter Tuerk provided training and consultation to project staff in therapeutic exposure techniques.
- 9/5/08: Project staff received training in (Clinician Administered PTSD Scale; CAPS) administration
- 11/6-11/8/08: Project staff attended the CAPS training seminar in Washington D.C.
- 1/9/09; 1/29/09: Dr. Marty Strachan and Ms. Julie Rossi provided a clinical overview of the protocol to therapists at Winn Army Community Hospital.

Other Clinical Activities

In addition to training and protocol development activities, throughout this reporting year, project staff have attended weekly clinical staffing meetings, supervision meetings, and multidisciplinary clinical treatment team meetings.

PART V: Personnel Activities

During the first quarter (4/1/08-6/30/08) all personnel activities we awaiting the release of funding. During the second quarter (7/1/08-9/30/08), project coordinators and therapists were hired, project staff completed MUSC and VA required research trainings, project consultants engaged in project training and decision making regarding

intervention and assessment components, consultants came to Charleston to meet with project investigators, therapists were trained in BATE and in the use of videophone equipment, relevant staff members were trained in conducting the assessment protocol, and relevant staff members attended clinical seminars conducted by project consultants. During the third quarter (10/1/09-12/31/08), a research interviewer was hired and attended a CAPS training in Washington, DC. Also, a research assistant was hired to complete data entry and other administrative activities.

PART VI: Administrative Activities

Administrative activities including amendments to the protocol, review board submission and approval dates, audit dates and results, and inventory management are documented below as a bullet-pointed timeline.

Amendments Submitted to the MUSC IRB:

- Amendment #1 was deleted and not submitted or approved
- Amendment #2 - PERSONNEL - Dr. Strachan was added to the study as project coordinator (Submitted 05/18/2008; Approved 05/22/2008)
- Amendment #3 – PROTOCOL and CONSENT REVISION - Sponsor recommended (Submitted 09/15/2008; Approved 09/18/2008)
- Amendment #4 - PERSONNEL - Samantha Rodman and Julie Rossi were added to study as project therapists (Submitted 09/13/2008; Approved 09/19/2008)
- Amendment #5 - - PERSONNEL - Wendy Muzzy was added as the principle IRB contact (Submitted 10/02/2008; Approved 10/07/2008)

- Amendment #6 - PERSONNEL - Karen May was added as the nurse/interviewer and Katherine Fidrych was added as a research assistant (Submitted 11/25/2008; Approved 12/12/2008)
- Amendment #7 - PERSONNEL - Added Dr. Kathryn Magruder and Derik Yeager as collaborators on the project (Submitted 12/10/2008; Approved 12/12/2008)
- Amendment #8 - PROTOCOL and CONSENT REVISION – changes to screening procedures to reflect VA standard of care; grammatical corrections to the informed consent document(Submitted 12/31/2008; Approved 01/09/2009)
- Amendment #9 - PROTOCOL and CONSENT REVISION –Expanded inclusion criteria to include PTSD and MDD; addition of alternate sites - WACH and Atlanta VA; using SKYPE as a videoconferencing option; allowing for videoconferencing to conduct assessments (Submitted 02/25/2009; Approved 03/13/2009)
- Amendment #10a - PROTOCOL and CONSENT REVISION –addition of MUSC as an alternate research site; $20 payment for post assessment (Submitted 03/27/2009; Approved 04/03/2009)
- Amendment #10b - PERSONNEL - Dr. Elizabeth Dismuke was added as a health economist (Submitted 03/27/2009; Approved 04/03/2009)

Submitted to the Research and Development Committee:

- 09/18/08 Submitted the DoD approved protocol along with the local IRB approval
- 10/03/08 Received R&D approval to recruit participants

- Note that all IRB amendments (listed above) have been reported and approved by the R&D committee at each monthly meeting

Internal and Institutional Audits:

- 01/21/09 – Internal audit of all study records and consents
- 02/27/09 –Health Services Research and Development's (HSR&D) compliance officer performed an informed consent audit – No errors were found on any of the consents or HIPAA forms
- 03/25/09 – Internal audit of all study records and consents

Other Administrative Activities:

- 8/19/08 - Video phones were ordered

PART VII: Other Research-Related Activities

Compliance Training

Between 9/3/08 and 9/12/08, project staff completed the MUSC required, Core Clinical Research Training. This two-week long course covered regulatory board (i.e., IRB, R & D committee) approval processes, informed consent and HIPAA policies, clinical research budgets and contractual agreements, maintaining regulatory files, adverse event reporting, recruitment and retention, research misconduct and clinical trials, and career development and local networking.

Additionally, project staff attended weekly research team meetings. Meetings covered protocol adherence, data management, creating the data base, randomization procedures and compliance and regulatory issues.

Consultation from Dr. Christopher Frueh

Dr. Frueh consulted with staff throughout the month of August and November regarding study procedures related to telemedicine and assessment. Specifically, Dr. Frueh assisted project staff in the selection of assessment measures, use of telemedicine equipment, safety procedures in the event of remote emergencies, and general operating procedures for clinical telemedicine care.

Submission to Conferences

During this reporting period, study staff submitted abstracts for poster presentations at the Military Health Research Forum (MHRF; 8/31-9/3/09, Kansas City) and the Association for Behavioral and Cognitive Therapies (ABCT; 11/19-11/22/09, New York City). Staff will present an overview of the project, description of the treatment manual, research method and design, and case study data.

Financials

	Apr '08 - Mar 09	Budget	$ Over Budget	% of Budget
Income				
4200 · Grants Income	215,496.77	389,522.30	-174,025.53	55.32%
Total Income	215,496.77	389,522.30	-174,025.53	55.32%
Expense				
50500 · Other Salaries & Wages	56,677.29	127,500.00	-70,822.71	44.45%
50550 · Fringe Benefits	5,036.10	33,787.50	-28,751.40	14.91%
67000 · Materials and Supplies	39,285.99	40,500.00	-1,214.01	97.0%
70500 · Travel	0.00	1,800.00	-1,800.00	0.0%
72200 · Consulting Fees	19,000.00	18,750.00	250.00	101.33%
72700 · Study Participant Compensation	783.60	2,000.00	-1,216.40	39.18%
75000 · Staff Training Registration	150.00			
80000 · Indirect Costs-IDC Admin Fee	39,401.91	67,321.13	-27,919.22	58.53%
80500 · MUSC Direct Costs	43,779.28	77,669.58	-33,890.30	56.37%
80600 · MUSC Indirect Costs	11,382.60	20,194.09	-8,811.49	56.37%
Total Expense	215,496.77	389,522.30	-174,025.53	55.32%
	0.00	**0.00**	**0.00**	**0.0%**

Key Research Accomplishments

- 4/1/08: Dr. Acierno receives award letter
- 4/1/08: MUSC approves protocol
- 7/15/08: Project coordinator and project therapist are hired
- 8/08-10/08: Project staff trained in behavioral activation and exposure; supplemental materials to manualized treatment protocol created.
- 9/3/08-9/12/08: Project staff attends compliance training
- 9/9/08: HRPO approves protocol
- 9/18/08: MUSC approves protocol
- 10/3/08: VA R&D committee approve protocol
- 10/6/08: Initiation of recruitment procedures
- 10/22/08: First participant assessed
- 10/30/08: First participant enrolled
- 11/1/08: Nurse interviewer hired
- 11/6/08-11/8/08: Project staff attends CAPS training in Washington D.C.
- 1/09: VA assessment system implemented
- 1/09-3/09: First wave of patients completes treatment phase
- 1/9/09; 1/27/09: Project staff provides clinical overview of the study to therapists at Winn Army Community Hospital
- 2/20/09: Project staff attend DOD-sponsored conference highlighting VHA/DOD research and clinical collaborations

Reportable Outcomes

There are no reportable outcomes at this time in terms of study findings.

Conclusion

Development of Collaboration Enhancement Strategies

On a broad level, an important outcome of this first year has been to develop an infrastructure that will facilitate future DOD/VA research collaborations. As the first DOD-funded therapeutic treatment study for PTSD at this facility, we have been contacted by several investigators, interested in pursuing DOD funding mechanisms for their research, but intimidated by the process. Indeed, as greater numbers of OIF/OEF service men and women are returning home, DOD/VA research collaborations will play an essential role in the advancement of mental health care for military populations. As such, project staff members are in the process of creating a manual that will detail practical strategies for enhancing DOD/VA research collaborations. Project staff will use this manual to conduct practical seminars for other VA investigators at this facility who are interested in pursuing DOD funding.

Directions for the Next Reporting Year

Continue recruitment and all study procedures via protocol.

References

There are no references cited in this report.

Appendices

None